



BREAKDOWN: LESSONS TO BE LEARNED FROM THE 2008 SALMONELLA SAINTPAUL OUTBREAK

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INTRODUCTION

The U.S. Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) declared the *Salmonella* Saintpaul outbreak of 2008 officially over on August 28, 2008, some three months after it began. During that time, more than 1,400 persons were reported infected, and if, as suggested by research, this represents an underreporting,¹ the outbreak may have sickened thousands of Americans. Although CDC and FDA initially pointed in early June to tomatoes as the cause of the outbreak based on epidemiological data, no contaminated tomato was ever found. In July, CDC and FDA identified jalapeno and serrano peppers as being responsible for illnesses, and the only microbiological evidence of food contaminated by *Salmonella* Saintpaul was, in fact, found in jalapeno and serrano peppers.² However, as a result of the initial identification of tomatoes as the vector for the disease, the tomato industry, a significant sector of this country's agriculture economy, was another major casualty. Estimates of the economic cost to that industry in Florida alone have been more than \$100 million and in Georgia close to \$14 million.³ A less tangible, but still very real, impact of the outbreak may well be its long-term effect on consumer confidence in fresh produce in general and fresh tomatoes in particular.

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Given the human, economic and public-health costs of this recent food borne-illness outbreak, therefore, it is critical to learn from it. In fact, members of Congress and representatives from the produce industry have called for post-mortem investigations of the outbreak, and senior FDA officials have promised a thorough and transparent accounting of the public-health system's response.⁴ This report represents the first extensive and in-depth review of the public record of the *Salmonella* Saintpaul outbreak. (See Appendix A) In conducting this review, the Produce Safety Project (PSP), an initiative of The Pew Charitable Trusts at Georgetown University, has attempted to frame questions that will be critical for any post-mortem analysis to consider and to identify issues that should be addressed. In doing so, three areas of concern have surfaced: policy, the public-health system's organization and outbreak response, and its communications with the media and the public.

EXECUTIVE SUMMARY

For this report, PSP reviewed all of the public statements and Web site postings of the CDC and FDA; the transcripts of the FDA/CDC media calls; press releases and Web site postings by state public-health departments and industry trade associations; and media coverage from around the country. In addition PSP staff attended and monitored the oversight hearings held by Congressional committees.

Based on that review, PSP calls on federal public-health officials to follow through on their commitment to undertake a thorough and comprehensive post-mortem analysis of the *Salmonella* Saintpaul outbreak and report their findings publicly. The analysis should focus on:

- The need for preventive safety standards for fresh produce.
- Reforms needed to address organizational and capacity shortcomings in the public-health system's response to foodborne-illness outbreaks at the local, state and federal levels.
- Procedures and systems needed to ensure accurate risk communication to the public and affected industries.

Preventive Safety Standards for Fresh Produce

FDA officials consistently pointed to this outbreak as further proof of the need for preventive safety controls for produce but said they need Congress to act. In fact, FDA, under its existing statutory authorities, has established similar preventive control systems through its Hazard Analysis and Critical Control Point (HACCP) regulations for seafood and juice, and has proposed on-farm safety measures for shell eggs.⁵ Moreover, in early 2007, FDA officials cited those same existing statutory authorities when they unsuccessfully sought approval from the Department of Health and Human Services (HHS) to move forward on produce-safety standards.⁶ The recent *Salmonella* Saintpaul outbreak shows the immediate need to establish preventive safety measures using existing legal authority.

Organization and Capacity

Questions about the food-safety system's lack of organization, capacity and coordination and their resulting impact on the effectiveness of the public-health response are raised by comparing the CDC's *Mortality and Morbidity Weekly Report* article⁷ on the outbreak (hereafter, "CDC Outbreak Report") with the public statements of FDA and CDC officials during the outbreak. For instance, the epidemic curve (or "epi curve") published in the CDC outbreak

report shows that some 50 percent of the confirmed cases began before the FDA nationwide consumer advisory on June 7 recommending that consumers avoid eating certain tomatoes. While there was a drop in cases after that announcement, it appears that the most sustained drop began around June 24. Maybe this drop was a factor of the incubation period for the illness, or maybe it points to an off-target intervention. A post-mortem analysis should examine this question. In addition, the discussion in the CDC outbreak report of cluster investigations in mid- to late-June raises questions about why FDA and CDC officials continued to maintain so steadfastly and for so long that tomatoes were the leading suspect for being the vector for *Salmonella* Saintpaul.

Risk Communications

From the beginning of the outbreak, public-health communication to the media and the public was disjointed and confusing. Five different agencies – two federal and three state – "announced" the outbreak over the course of four days with significant variations in facts and messages. Then, three weeks into the public-communications effort, the CDC significantly changed – with no explanation – the manner in which it presented outbreak data, from raw number of cases in a state, to cases per million in a state, to a range of cases per state. While the change in presentation of data by CDC may have been worthwhile, it begs the question of why established procedures were not in place before this outbreak began. These failures in communication may well have contributed to the public's decision to stop buying and eating tomatoes altogether in June and July.

To date, much of the analysis of the outbreak has focused on the "traceback," FDA's attempt to locate the source of contamination.⁸ As important as that discussion is, if the post-mortem analyses are limited to that aspect, deeper and even more fundamental structural and organizational shortcomings risk being neglected. Indeed, these shortcomings in the nation's food-safety system are not new, having been documented repeatedly during the past decade by many expert bodies, including the National Academies of Science,⁹ the Government Accountability Office,¹⁰ and the FDA's Science Board.¹¹ The key question here is whether the nation's food-safety policymakers will learn the lessons of this outbreak and fix the system. To learn those lessons, they need to undertake a thorough, in-depth and transparent review of what went right this past summer, what went wrong, what could be done better, and what should never happen again.